IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

NEFTEL et al Atty. Ref.: 2590-147

Appl. No. 10565810 (9705) TC/A.U. 3767

Filed: February 9, 2006 Examiner: Larry Ross Wilson

For: A SYSTEM FOR PERFORMING PERIOTONEAL DIALYSIS

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Mail Stop Appeal Brief – Patents December 15, 2010
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF and INTERVIEW SUMMARY STATEMENT

Appellant hereby appeals to the Board of Patent Appeals and Interferences from the last decision of the Examiner and requests an extension to file this Brief up to and including December 15, 2010 (the extension fee is being paid with this filing). The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

With respect to the Interview Summary dated July 27, 2010, applicant provides the following Interview Summary Statement. As stated in the Interview, applicant disagrees with the Examiner's contentions. Contrary to the Examiner's

contentions, Kamen (USP 5350357) specifically discloses a device that requires two membrane pumps that are contained within the liquid distribution system of Kamen. This nothing like the claimed invention that requires the use of a peristaltic pump that is separate from the liquid distribution system. Also contrary to the Examiner's contention, Kamen's device has no unidirectional ports that are connected to the Kamen pumps. In complete contrast to Kamen, the claimed liquid distribution system is separate from the claimed partial peristaltic pump and the claimed ports connected to the claimed pump are unidirectional. Kamen teaches away from these claimed features.

(I) REAL PARTY IN INTEREST

The real party in interest and assignee is DEBIOTECH S.A., which is a Swiss corporation.

(II) STATEMENT OF RELATED CASES

The appellant, the undersigned, and the assignee are not aware of any related appeals, interferences, or judicial proceedings (past or present), which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(III) STATUS OF CLAIMS

Claims 1-9 and 11-66 are pending in this application and are on appeal.

Claim 10 has been cancelled without prejudice during prosecution.

(IV) STATUS OF AMENDMENTS

All amendments filed prior to the Final Office Action of March 18, 2010, have been entered. No amendments have been requested or entered after the Final Office Action.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1, 53, and 66 are the only independent claims. The easiest way to summarize the claims is to parse them in the following manner. Parenthetical reference numbers are contained in the claims, which should assist the Board.

Claim 1: A system for performing fluid administration on a patient comprising:

- a partial peristaltic pump (1) (page 6, para 1; Fig. 1),

- a liquid distribution system (2) that is a cartridge and that is separate from said pump and that is connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa (page 6, para 1; Fig. 1, 1a, 1b),

- liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1) (page 6, para 2; Fig. 1, 1a, 1b),

- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4) (page 6, para 2; Fig. 1, 1a, 1b),

wherein said liquid distribution system (2) comprises two distinct hub chambers (7,8) which are separated by a space, the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26), the second hub chamber (8) including at least one patient port (18) or warmer port (16) with dedicated valve

means and one pump outlet (27), said system further comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa (page 6; Figs 1, 1a, 1b, 3) and

wherein all ports of the liquid distribution system that communicate with the pump are unidirectional such that liquid only flows in one direction (page 8, Figs 1, 1a, 1b).

Claim 53: A system for performing fluid administration on a patient comprising a flexible membrane (13) forming a valve seat characterized by the fact that said membrane includes a clipping mechanism adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode (page 10; Fig. 11-13; page 15; Fig. 32).

Claim 66: A disposable cassette for use in performing fluid administration on a patient comprising:

- a partial peristaltic pump (1) (page 6, para 1; Fig. 1),

- a liquid distribution system (2) in a substantially rectangular-shaped member that is separate from said pump and that is abutted to a side of said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa (page 6; Figs 1, 1a, 1b, 3),

- liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1) (page 6, para 2; Fig. 1, 1a, 1b),

- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4) (page 6, para 2; Fig. 1, 1a, 1b),

wherein said liquid distribution system (2) comprises a first hub chamber and a distinct second hub chamber (7,8) which are separated by a space (page 6; Figs 1, 1a, 1b, 3),

the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26) (page 6; Figs 1, 1a, 1b, 3),

the second hub chamber (8) including at least one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27) (page 6; Figs 1, 1a, 1b, 3),

said system further comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa (page 6; Figs 1, 1a, 1b, 3), and

wherein all ports of the liquid distribution system that communicate with the pump are unidirectional ports (page 8, Figs 1, 1a, 1b).

For the means plus function claim language:

In claims 1 and 66, the liquid supply means (3) for supplying liquid to a patient can be a bag (page 6, para 2; Fig. 1).

In claims 1 and 66, the dedicated valve means (9) can be a liquid supply port with a valve 9 (pages 3 and 6; Fig. 3); and the dedicated valve means (10) can be a patient port with valve 10 (pages 3 and 6; Fig. 3).

(VI) GROUNDS OF REJECTION TO BE REVIEWED

1. Are claims 1, 2, 8, 9, 17, 19-21, 26, 30, 41-45, 48, 54, 56-58, 61, 64, 65 and 66 properly rejected as being obvious over Kamen (USP 5350357) in view of Neftel (USP 5518378)?

2. Are claims 3-5 and 11 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Goldrath (USP 5437629)?

3. Are claims 6-7 properly rejected as being obvious over Kamen as modified by Neftel and Goldrath and further in view of Suzuki (European Patent Application Publication EP1195171 A2)?

4. Are claims 40, 47, 49, 51 and 52 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Suzuki?

5. Are claims 12, 35-39, 50 and 55 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Williams (USP 4758228)?

6. Are claims 15-16 properly rejected as being obvious over Kamen as modified by Neftel in view of Moubayed (USP 5683233)?

7. Are claims 27-28 properly rejected as being obvious over Kamen as modified by Neftel and Williams and further in view of Moubayed?

8. Is claim 29 properly rejected as being obvious over Kamen as modified by Neftel, Williams and Moubayed and further in view of McFarland (USP 2684829)?

9. Is claim 13 properly rejected as being obvious over Kamen as modified by Neftel and Williams and further in view of Uno (USP 4530647)?

10. Is claim 14 properly rejected as being obvious over Kamen as modified by Neftel and Williams and further in view of Robinson (USP 5840069)?

11. Is claim 18 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Dominiak (USP 5478211)?

12. Are claims 31, 34, 46 and 59 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Epstein (USP 4828545)?

13. Is claim 60 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Huber (USP 4952372)?

14. Are claims 62-63 properly rejected as being obvious over Kamen as modified by Neftel and further in view of Peabody (USP 4586920)?

15. Are claims 22, 32 and 33 properly rejected as being obvious over Kamen as modified by Neftel and further in view of McFarland?

16. Is claim 53 properly rejected as being obvious over Kamen in view of McFarland?

17. Are claims 23-25 properly rejected as being obvious over Kamen in view of Neftel and McFarland and further in view of Suzuki?

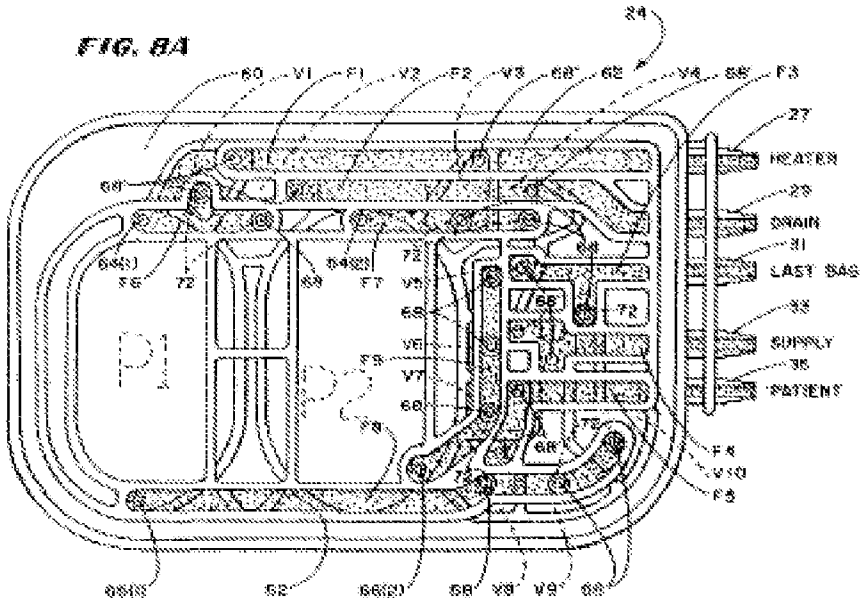
(VII) ARGUMENT

Claims 1-9 and 11-66 are pending in the application. Only claims 1, 53, and 66 are independent. For the convenience of the Board, the following argument section focuses first on claims 1 and 66, which have similar elements in combination that are not disclosed or rendered obvious by the cited prior art, then focuses on claim 53.

Independent Claims 1 and 66 are Patentable

All of the rejections of claims 1 and 66 (and the claims dependent on claim 1) attempt to combine the teachings of the primary reference (Kamen) with a secondary reference (Neftel). For at least the following reasons, Kamen teaches away from the claimed invention, and there is no reason why a person skilled in the art would or could insert the Neftel peristaltic pump into the Kamen device in order to arrive at applicant's claimed invention. As a result, there is no prima facie case of obviousness, and the rejections should be reversed.

Applicant's claimed invention requires a partial peristaltic pump (1) that is **separate** from a liquid distribution system (2). See applicant's Figures 1, 1a, 1b, and 3. In contrast, Kamen's device requires two membrane pumps (see P1 and P2 in Kamen's Figure 8A) **contained within** a liquid distribution system. For the convenience of the Board, Kamen's Figure 8A is shown below. Thus, the Kamen assembly is quite different in structure and function than the claimed invention.



Moreover, Kamen's system does not have the applicant's claimed **unidirectional ports**. The Examiner contends that Kamen's ports are "unidirectional" because they are allegedly "unidirectional for part of the cycle." Respectfully stated, this makes no sense and is a misinterpretation of the meaning of "unidirectional" to those of skill in the art. "Unidirectional" ports means that fluid flows in only one direction during the device's operation. If this was not the case, what would bidirectional mean? Would this mean that fluid is flowing in

both directions at the same time – which is impossible in any operational pump port. In other words, "unidirectional" according to the Examiner would cover all operational pump ports even though those pump ports pass fluid in different directions at different times.

Properly stated, Kamen must have fluid flowing in one direction through its pump ports at one time and then another direction at another time. These types of ports are **not** known as "unidirectional" ports. Instead, they are "**bidirectional**" ports.

Kamen's ports are undoubtedly "**bidirectional**" – as well known to those of skill in the art and as clearly shown in Kamen. Some of the best evidence of the "bidirectional" ports is illustrated in Kamen's Figures 32 and 33 that, respectively, show a fill phase and a dwell phase. Those Figures contain arrows which show the direction of the liquid. As undeniably shown in those Figures, for the same ports, the liquid direction is **opposite** (**bidirectional**) between Figure 32 and Figure 33. More specifically, in Figure 32, the liquid is flowing through the following successive elements F1 -> F6 -> P1 -> F8 -> F5. In contrast, in Figure 33, the liquid is flowing through the following successive elements F4 -> F8 -> P1 -> F6 -> F1 in figure 33. This additional bidirectional/unidirectional difference between Kamen's system and the applicant's claimed system **further demonstrates that**

applicant's claimed apparatus is structurally and functionally different than Kamen's apparatus.

For at least the foregoing reasons, Kamen teaches away from the claimed invention because Kamen's apparatus requires **two membrane pumps contained within** its **liquid distribution system**, and Kamen's ports are **bidirectional** ports. In contrast, the claimed invention requires that the **partial peristaltic pump** be **separate** from the **liquid distribution system** and that the **ports are unidirectional**. These features are nowhere disclosed or suggested by Kamen itself or in any reasonably apparent combination with any other secondary reference.

Correctly stated, Kamen teaches away from the claimed design. Indeed, if Kamen were modified in the fashion suggested by the Examiner, then it would destroy the design of the Kamen device. This confirms improper hindsight reconstruction.

In summary, there is no prima facie case of obviousness and the rejections of claims 1 and 66 (and all of the claims depending from claim 1) should be reversed.

Independent Claim 53 is Patentable

Claim 53 stands rejected as being obvious over Kamen in view of McFarland. Claim 53 requires a flexible membrane forming a valve seat characterized by the fact that said membrane includes a clipping mechanism

adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode. The primary reference, Kamen, fails to teach or suggest "a clipping mechanism adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode." The secondary reference, McFarland, does not overcome this deficiency. There is no reasonably apparent way to use any alleged clipping mechanism in McFarland with the Kamen device and arrive at the claimed invention. As a result, the rejection should be reversed.

CONCLUSION

Applicant respectfully requests the Board to reverse the final rejections and pass the subject application to issue.

Respectfully submitted,

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(VIII) CLAIMS APPENDIX

1. (rejected) A system for performing fluid administration on a patient comprising:

- a partial peristaltic pump (1),

- a liquid distribution system (2) that is a cartridge and that is separate from said pump and that is connected to said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,

- liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1),

- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),

wherein said liquid distribution system (2) comprises two distinct hub chambers (7,8) which are separated by a space, the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26), the second hub chamber (8) including at least one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27), said system further comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa and

wherein all ports of the liquid distribution system that communicate with the pump are unidirectional such that liquid only flows in one direction.

2. (rejected) System according to claim 1 wherein said second hub chamber (8) furthermore includes at least one drain port with dedicated valve means (11), said control means being also arranged to close said patient port (18) of the second hub chamber (8) when said drain port (11) is open and vice versa.

3. (rejected) A system according to claim 1 wherein said liquid distribution system (2) only includes two hub chambers (7,8).

4. (rejected) A system according to claim 1 furthermore comprising a warmer system (28), a cavity (17) including a warmer port (19) and a patient port (16), said patient port (18) of the second hub chamber (8) being connected to said warmer port (19) via said warmer system (28).

5. (rejected) A system according to claim 4 wherein said warmer system (28) is a warmer in-line.

6. (rejected) A system according to claim 5 wherein said warmer in-line comprises a warming plate contained therein, such warming plate being covered by a warming pouch.

7. (rejected) A system according to claim 6 wherein said warming pouch is composed of a liquid channel which forces the liquid to be maintained within such warmer for a certain duration at a given flow rate.

8. (rejected) A system according to claim 1 wherein said first hub chamber (7) includes several liquid supply ports with respective valve means (9).

9. (rejected) A system according to claim 8 wherein said liquid supply ports (9) are connected to respective liquid supply means each having a different kind of liquid.

10. (canceled)

11. (rejected) A system according to claim 1 wherein said peristaltic pump is unidirectional.

12. (rejected) A system according to claim 1 wherein said pump (1) is composed of a tubing and rolling surface on which the tubing is compressed once the pump and liquid distribution system are inserted into a pumping device containing rollers.

13. (rejected) A system according to claim 12 where said rollers (22) are of a conical shape in such a way as to be self inserted in the pump race, i.e. without any other mechanism.

14. (rejected) A system according to claim 12 where said rollers are of a spherical shape.

15. (rejected) A system according to claim 1 wherein said pump (1) comprises a flexible or partially flexible channel and a series of movable finger elements successively situated above said channel, each finger element being movable along a direction which is substantially perpendicular to said channel, all finger elements being adapted to induce a peristaltic movement along said channel.

16. (rejected) A system according to claim 15 wherein each finger element comprises a convex basis adapted to conform with the channel inner surface and a shaft adapted to be linked to an actuator.

17. (rejected) A system according to claim 1 wherein said pump (1) and said liquid distribution system (2) are fixed together to form a single assembly.

18. (rejected) A system according to claim 17 wherein said pump (1) is fixed to said liquid distribution system (2) by vibration attenuation means in order to minimize the vibration on the liquid distribution system (2) when the pump is operating.

19. (rejected) A system according to claim 1 wherein all hub chambers, including said ports and ports, are made within one single part.

20. (rejected) A system according to claim 19 wherein said single part is an injected part of plastic material.

21. (rejected) A system according to claim 1 wherein each hub chamber (7,8) is closed with an upper wall made of a flexible membrane (13), said membrane including valve elements (39) situated above each of said port or port with valve means, said valve elements (39) being designed to close said port or port when the membrane (13) moves downwardly.

22. (rejected) A system according to claim 1 wherein each hub chamber (7,8) is closed with an upper wall made of a flexible membrane (13), said membrane including clipping means adapted to clip elements.

23. (rejected) A system according to claim 22 wherein said membrane is molded.

24. (rejected) A system according to claim 23 wherein said membrane is made out of any of the following materials: silicone or polyurethane.

25. (rejected) A system according to claim 24 wherein said membrane includes liquid tight joints.

26. (rejected) A system according to claim 21 wherein said membrane extends in such a way that it also covers said pump (1).

27. (rejected) A system according to claim 12 wherein said pump (1) comprises a flexible or partially flexible channel, a membrane covering said channel along an oblique plane, in order to allow a peristaltic movement induced by rollers or similar elements.

28. (rejected) A system according to claim 27 comprising individual actuators or a cam adapted to induce a peristaltic movement.

29. (rejected) A system according to claim 28 wherein said individual actuators are adapted to be actuated by fingers which are clipped to said membrane.

30. (rejected) A system according to claim 1 wherein said liquid distribution system includes liquid tight joints arranged in such a manner that they allow a liquid tight connection between said liquid distribution system and a membrane situated on it.

31. (rejected) A system according to claim 21 wherein said membrane contains protruding elements designed for a liquid tight connection between said hub chambers.

32. (rejected) A system according to claim 21 wherein each of said valve elements (39) is designed to be clipped to an actuator (34) arranged above said membrane (13).

33. (rejected) A system according to claim 32 wherein each of said valve elements comprises a cavity designed to receive and hold the plunger of an actuator, said cavity having an height which substantially corresponds to at least the valve displacement.

34. (rejected) A system according to claim 21 wherein said membrane (13) is press-fitted along its external border to the liquid distribution system, the membrane (13) being furthermore held by a frame (14) .

35. (rejected) A system according to claim 21 wherein said membrane (13) contains a portion (15) which is forming part of a pressure sensor.

36. (rejected) A system according to claim 35 wherein the active area of said pressure sensor is designed to be more flexible than the remaining area.

37. (rejected) A system according to claim 35 wherein said pressure sensor has the shape of a disc of which the periphery is gripped, said disc furthermore comprising an annular ply.

38. (rejected) A system according to claim 35 wherein said pressure sensor is situated on the patient line, independently from said hub chambers.

39. (rejected) A system according to claim 35 furthermore comprising a second pressure sensor, said second pressure sensor being in connection with the first hub chamber.

40. (rejected) A system according to claim 1 wherein said liquid distribution system includes an air sensor situated on the patient conduit side.

41. (rejected) A system according to claim 1 comprising a cartridge loading mechanism which allows a tight connection between the membrane and the valves and the liquid distribution system.

42. (rejected) A system according to claim 1 comprising flow blocking means adapted to block the flow towards or from the liquid distribution system when this latter one is released out of the system.

43. (rejected) A system according to claim 42 wherein said blocking means is a mechanical clamp situated on the patient line.

44. (rejected) A system according to claim 42 wherein said blocking means is a lip valve situated on the patient line, the system furthermore comprises a movable pin adapted to open said lip valve when the liquid distribution system is released out of the system.

45. (rejected) A system according to claim 21 comprising a molded frame adapted to cover the space between said hub chambers, each space above said hub chambers being covered by a flexible membrane.

46. (rejected) A system according to claim 45 wherein said molded frame is fixed to said liquid distribution system by ultrasound, laser welding, gluing or thermal bonding.

47. (rejected) A system according to claim 45 wherein said molded frame is at least partially made of silicone or polyurethane.

48. (rejected) A system according to claim 45 wherein said frame, membrane and liquid distribution system are obtained by overmolding technique.

49. (rejected) A system according to claim 21 using a double layer membrane adapted to prevents spallation or particule release into the fluid during use.

50. (rejected) A system according to claim 1 furthermore comprising a window for detecting correct positioning of the tube.

51. (rejected) A system according to claim 21 furthermore comprising a rigid plate (67) which covers and holds the membrane (13), said rigid plate (67) comprising holes (70) adapted to let moving elements passing through.

52. (rejected) A system according to claim 51 wherein said rigid plate (67) includes pins (68) situated on the membrane side, said pins (68) being adapted to be fixed on the liquid distribution system (2).

53. (rejected) A system for performing fluid administration on a patient comprising a flexible membrane forming a valve seat characterized by the fact that said membrane includes a clipping mechanism adapted to be reversibly attached to a moving actuator in such a way that the membrane movement can be controlled in a push and a pull operation mode.

54. (rejected) A liquid distribution system (2) for a system performing fluid administration on a patient as defined in claim 1.

55. (rejected) A pressure sensor for a system for performing fluid administration on a patient as defined in claim 35.

56. (rejected) Method of use of the system as defined in claim 1 wherein said patient port (10) is closed when said liquid supply port (9) is open and vice versa.

57. (rejected) Method according to claim 56 wherein the pressure is always maintained positive with respect to the drain.

58. (rejected) Method according to claim 56 wherein said liquid is always pumped in the same direction.

59. (rejected) Method according to claim 56 consisting of sensing the liquid pressure entering and exiting the liquid distribution system and, if necessary, correct the pump flow rate in accordance with the pressure difference.

60. (rejected) Method according to claim 56 consisting in regulating the pump flow rate according to a known predetermined alteration of the flow rate by aging of the tubing.

61. (rejected) Method according to claim 56 wherein the drain phase is a function of the drain speed, said drain phase being ended when the speed is reaching a certain value based on the patient peritoneal cavity pressure measurement.

62. (rejected) Method according to claim 56 wherein the peritoneal volume filled during a cycle is a function of the intra-peritoneal pressure.

63. (rejected) Method according to claim 62 wherein the peritoneal cavity is partially emptied as soon as the pressure has reached a predefined threshold.

64. (rejected) Method according to claim 56 consisting in the use of a low Natrium concentration liquid for the last exchange cycle to improve ultra-filtration.

65. (rejected) Use of a system as defined in claim 1 for peritoneal dialysis comprising:

selecting a liquid,

supplying the liquid to a patient via use of the system for peritoneal dialysis.

66. (rejected) A disposable cassette for use in performing fluid administration on a patient comprising:

- a partial peristaltic pump (1),

- a liquid distribution system (2) in a substantially rectangular-shaped member that is separate from said pump and that is abutted to a side of said pump (1) in such a way that liquid can flow from the liquid distribution system (2) to the pump (1) and vice versa,

- liquid supply means (3) for supplying liquid to a patient (4) via said liquid distribution system (2) and said pump (1),

- a patient conduit (5) adapted for connecting said liquid distribution system (2) to a patient (4),

wherein said liquid distribution system (2) comprises a first hub chamber and a distinct second hub chamber (7,8) which are separated by a space,

the first hub chamber (7) including at least one liquid supply port with dedicated valve means (9), one patient port with dedicated valve means (10) and one pump inlet (26),

the second hub chamber (8) including at least one patient port (18) or warmer port (16) with dedicated valve means and one pump outlet (27),

said system further comprising control means arranged to close said patient port (10) of the first hub chamber (7) when said liquid supply port (9) is open and vice versa, and

wherein all ports of the liquid distribution system that communicate with the pump are unidirectional ports.

(IX) EVIDENCE APPENDIX

Not Applicable.

(X) RELATED PROCEEDINGS APPENDIX

Not Applicable.